

**REMARKS**

Reconsideration of this application is respectfully requested.

**STATUS OF THE CLAIMS**

Following entry of this Amendment, claims 1-11 and 18-33 are pending pending. Claims 1 and 11 have been amended.

Support for the amended claims is as follows:

Claim 1: page 25, lines 20-23.

Claim 11: page 26, lines 29-37 and page 27, lines 1-5.

No extra claims fees are believed owed as a result of the amended claim, but the Commissioner is authorized to charge the above-mentioned deposit account the required amount in the event that is incorrect.

**INFORMALITIES**

The Examiner objects to claims 1, 2, and 5-11 because the claims contain an amino acid sequence, i.e. TrpAspLysGlu, without the required sequence identifier.

Applicants have submitted a new sequence listing with SEQ ID NO: 42 listing the amino acid sequence.

Applicants have also amended the specification at page 5, line 1 to include the term "SEQ ID NO: 42" following the description of the amino acid sequence.

**REJECTION UNDER 35 U.S.C. §101**

Claims 1-4, 8, 10, and 11 are rejected under 35 U.S.C. §101 on the basis that the claimed invention is directed to non-statutory subject matter. Reconsideration of the rejection is respectfully requested.

The Examiner states that "there is no recitation that the proteins are isolated/purified" as a basis that these claims read on products of nature. Applicants respectfully point out that the nucleotide sequence of SEQ ID NO: 3 has been modified by the removal of the sequence that encodes the leader and the fatty acid attachment site, cysteine 29, and also by the conversion of 6 TGA codons to TGG codons. The modifications to the mhp3 gene encode the amino acid sequence of SEQ ID NO: 4 and yields a truncated form of the Mhp3 protein that lacks the signal

peptide that is observed in the wild-type and seen in nature. The recombinant protein, represented by SEQ ID NO: 4 is therefore statutory subject matter because it is a protein not found in nature.

Applicants assert that the amendment to claim 11 that claims SEQ ID NO: 2 also addresses this rejection. The claim as now presented is drawn to the isolated immunogenic protein and to fragments of the immunogenic protein. Applicants respectfully refer the Examiner to page 26, lines 29-37 and page 27, lines 1-5 for a detailed description of the expression and isolation of a recombinant form of this protein.

In view of these arguments, Applicants request that the rejection of claims 1-4, 8, 10, and 11 under 35 U.S.C. §101 be withdrawn.

**REJECTION UNDER 35 U.S.C. §112, 2<sup>nd</sup>**

Claim 11 is rejected under 35 U.S.C. §112, 2<sup>nd</sup> as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendment to claim 11, the presently pending claim is submitted to not be indefinite. Reconsideration of the rejection is respectfully requested.

According to the Examiner, the instant specification does not define or teach guidelines for determining variants or derivatives thereof. Applicants have amended claim 11 by deleting the phrase "variant or derivative thereof." Following this amendment to claim 11, Applicants assert that this rejection is overcome. Applicants also refer the Examiner to p. 11, lines 14-18 and lines 22-26; p. 12, lines 33-36; and, p. 13, lines 1-2 in the specification for a definition of the term "fragment."

In view of the above, Applicants request that the rejection of claim 11 under 35 U.S.C. §112, 2<sup>nd</sup> be withdrawn.

**REJECTION UNDER 35 U.S.C. §112, 1<sup>st</sup>**

Claim 10 is rejected under 35 U.S.C. §112, 1<sup>st</sup> as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In view of the disclosure made by the Applicant disclosing the composition of claim 10, Applicants submit that it is enabled and reconsideration of the rejection is respectfully requested.

The Examiner states that Claim 10 which is drawn to a composition comprising said protein of claim 1, a pharmaceutically acceptable carrier, and further comprising at least 1 polypeptide selected from the groups consisting of *M. hyopneumoniae* P46, P65, P97, and P102, is not supported. In response thereto, Applicants refer the Examiner to page 18, lines 25-32 for a disclosure of the *M. hyopneumoniae* P46, P65, P97, and P102 proteins.

Also, Applicants refer the Examiner to page 5, lines 12-13, page 10, lines 25-28, and page 13, lines 21-27 for a disclosure of the combination claimed in claim 10. Applicants argue that the composition as claimed in claim 10 was sufficiently described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention commensurate with the scope of the instant claim.

Further, the Examiner states that the instant specification teaches production of a fusion protein, thiodoxin-Mhp3, but does not teach any composition commensurate with the scope of the instant claim. Applicants respectfully refer the Examiner to page 14, lines 3-6 and lines 31-37; and page 15, lines 1-24 for a detailed disclosure describing the various methods that can be used for the production of fusion proteins. Applicants assert that the specification sufficiently describes the methods used to generate the fusion proteins and that taken alone or in combination with the other techniques described one skilled in the art could have used these methods to generate a fusion protein commensurate with the scope of the instant claim.

In view of the above, Applicants assert that the presently claimed invention is enabled in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants therefore request that the rejection of claim 10 under 35 U.S.C. §112, 1<sup>st</sup> be withdrawn.

#### **REJECTION UNDER 35 U.S.C. §112, 2<sup>nd</sup>**

Claims 1-11 are rejected under 35 U.S.C. §112, 2<sup>nd</sup>, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that the claims are drawn to a protein which "does not have a fatty acid acylated cysteine followed by the amino acid sequence TrpAspLysGlu". However, it is unclear what are the metes and bounds of "followed", i.e., immediately following, or within a nondesignated number of residues.

In response thereto, Applicants point out that in the wild-type amino acid sequence, the cysteine at position number 29 is immediately followed by the Trp Asp Lys Glu amino acid sequence. In the recombinant protein of the present invention as shown in SEQ ID NO: 4 the cysteine is no longer at position number 29 and the amino acid sequence Trp Asp Lys Glu is also not present in position number 30. The term "followed" was used by Applicants as a way to describe the cysteine residue, i.e. a cysteine followed by Trp Asp Lys Glu. Applicants have amended claim 1 by adding to the claim the residue position of the removed cysteine. Further, Applicants respectfully point out that the absence of the cysteine residue at position 29 results in a recombinant Mhp3 protein that lacks a signal sequence and the necessary signal for lipid modification. The absence of the signal sequence allows for the efficient and high yield expression of Mhp3 for use in vaccines (see page 10, lines 11-14). This recombinant protein is encoded by SEQ ID NO: 4 and lacks the cysteine in position 29 as found in the wild-type. Following the amendment to claim 1, Applicants assert that this rejection should be withdrawn.

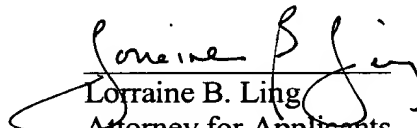
In view of the above, Applicants assert that claims 1-11 distinctly claims the subject matter that Applicants regard as the invention and request that the rejection of claims 1-11 under 35 U.S.C. §112, 2<sup>nd</sup> be withdrawn.

### CONCLUSION

Applicant submits that this application is now in condition for allowance. Issuance of a notice to that effect is earnestly solicited.

Respectfully submitted,

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Lorraine B. Ling  
Attorney for Applicants  
Reg. No. 35,251

Pfizer, Inc  
Patent Department, 5th Floor  
150 East 42nd Street  
New York, NY 10017  
(212) 573-2030

**VERSION OF CLAIMS SHOWING**  
**CHANGES**  
**DO NOT ENTER**

Amend claims 1 and 11 as follows:

1. (Amended) A protein having an amino acid sequence comprising at least 30 contiguous amino acids of SEQ ID NO: 4, wherein said protein does not have a fatty acid acylated cysteine **in position 29** followed by the amino acid sequence Trp Asp Lys Glu, and does not have a C-terminal homoserine lactone.

11. (Amended) An **isolated** immunogenic protein having an amino acid sequence as depicted in SEQ ID NO: 2, or a fragment[, **variant or derivative thereof,**] **of the immunogenic protein**, wherein the immunogenic protein does not have a fatty acid acylated cysteine followed by the amino acid sequence Trp Asp Lys Glu, and does not have a C-terminal homoserine lactone.